

BIOLOGICALS AND INTERCHANGEABLE BIOLOGICS

Strategic Elements



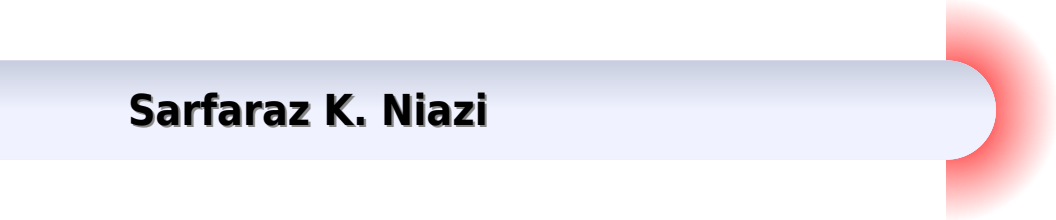
Sarfaraz K. Niazi



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Biosimilars Interchangeable Biologics Strategic Elements

Sarfaraz K. Niazi



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Biosimilars and Interchangeable Biologics Sarfaraz K. Niazi, 2018-10-30 What's the Deal with Biosimilars Biosimilars are gaining momentum as new protein therapeutic candidates that can help fill a vital need in the healthcare industry The biological drugs are produced by recombinant DNA technology that allows for large scale production and an overall reduction time in costs and development Part of a two volume set that covers varying aspects of biosimilars Biosimilars and Interchangeable Biologics Strategic Elements explores the strategic planning side of biosimilar drugs and targets issues surrounding biosimilars that are linked to legal matters This includes principal patents and intellectual property regulatory pathways and concerns about affordability on a global scale It addresses the complexity of biosimilar products and it discusses the utilization of biosimilars and related biological drugs in expanding world markets Of specific interest to practitioners researchers and scientists in the biopharmaceutical industry this volume examines the science technology finance legality ethics and politics of biosimilar drugs It considers strategic planning elements that include an overall understanding of the history and the current status of the art and science of biosimilars and it provides detailed descriptions of the legal regulatory and commercial characteristics The book also presents a global strategy on how to build take to market and manage the next generation of biosimilars throughout their life cycle [Biosimilars and Interchangeable](#)

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Analysis provides an opportunity to understand the non linearity of biological systems and its application in various areas of science primarily pharmaceutical sciences This book will benefit professionals in pharmaceutical industries academia and policy who are interested in an entirely new approach to how we will treat disease in the future Key Features Addresses a new approach of nonlinear analysis Applies a theory of projection to chalk out the future instead of basing on linear evolution Provides an opportunity to better understand the non linearity in biological systems and its applications in various areas of science primarily pharmaceutical sciences Helps change the thought process for those looking for answers to their questions which they do not find in the linear relationship approach Encourages a broader perspective for the creative process of drug development

Handbook of Preformulation Sarfaraz K. Niazi, 2019-03-22 Preformulation studies are the physical chemical and biological studies needed to characterize a drug substance for enabling the proper design of a drug product whereas the effectiveness of a drug product is determined during the formulation studies phase Though the two disciplines overlap in practice each is a significantly distinct phase of new drug development Entirely focused on preformulation principles this fully revised and updated Handbook of Preformulation Chemical Biological and Botanical Drugs Second Edition provides detailed descriptions of preformulation methodologies gives a state of the art description of each technique and lists the currently available tools useful in providing a comprehensive characterization of a new drug entity Features Addresses the preformulation studies of three different types of new active entities chemical biological and botanical which is the latest established class of active ingredient classified by the FDA Illustrates the activities comprised in preformulation studies and establishes a method of tasking for drug development projects Includes extensive flow charts for characterization decision making Gives extensive theoretical treatment of principles important for testing dissolution solubility stability and solid state characterization Includes over 50% new material

Patents as an Incentive for Innovation Rafal Sikorski, Żaneta Zemła-Pacud, 2021-02-16 Patents as an Incentive for Innovation Edited by Rafal Sikorski licensing on fair reasonable and non discriminatory FRAND terms the supplementary protection certificate SPC manufacturing waiver patent eligibility of artificial intelligence related inventions excessive enforcement of patents by patent assertion entities enforcement of second medical use innovations the so called farmer s privilege the farm save seed exemption and breeders rights international trade regulations and their influence on patent systems human enhancement technologies and the consequences of patenting them specifics of patent protection for biologic medicines challenges posed by artificial intelligence for the disclosure requirement in patent law and standard essential patent licensing particularly in the context of the 5G standard Perspectives taken into consideration by the authors include protectability criteria length and scope of the granted protection mechanisms for dealing with the friction between generalized application and specialized concerns and rights enforcement These aspects are analysed on the domestic international and global levels The COVID 19 pandemic has highlighted the urgent need to strike the right balance between innovation and access in healthcare and other technologies a need rooted in patent law Because

the problems discussed and solutions offered in this collection of expert essays are of tremendous practical and cultural significance the book will be of immeasurable value to practitioners policymakers and researchers in patent law and other fields of intellectual property law

Biosimilarity Sarfaraz K. Niazi,2018-10-03 Summary The focus of this book is on how the U S FDA will approve biosimilar drugs as learned from recent approvals by the FDA Understanding the limitations of the statutory limits and non inferiority testing are presented as tools to obviate patient trials and minimize testing of immunogenicity An in depth scientific mathematical and statistical view of the tools required to establish biosimilarity of biological drugs of different complexity a must for every developer of biosimilars Features First comprehensive analysis based on new guidelines and approval packages of several biosimilars Presents the first approach to challenge FDA in reducing or eliminating any testing in patients Provides a comprehensive understanding of the U S statutory requirements vis a vis the regulatory guidelines Provides model CQA and Analytical Similarity testing protocols for cytokines and monoclonal antibodies Allow creation of a fast to market pathway to develop biosimilars

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition Sarfaraz K. Niazi,2019-12-06 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Four Semisolid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing With thoroughly revised and expanded content this fourth volume of a six volume set compiles data from FDA and EMA new drug applications patents and patent applications and other sources of generic and proprietary formulations including author s own experience to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting A must have collection for pharmaceutical manufacturers educational institutions and regulatory authorities this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent Features Largest source of authoritative and practical formulations cGMP compliance guidance and self audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing bioequivalence testing and full compliance with drug product safety elements Written by a well recognized authority on drug and dosage form development including biological drugs and alternative medicines

New Horizons in Health-Promoting Technologies: From Development to Rational Use Luciane Cruz Lopes,Cristiane De Cássia Bergamaschi,Silvio Barberato-Filho,Marcus Tolentino Silva,Brian Godman,2020-10-08 This eBook is a collection of articles from a Frontiers Research Topic Frontiers Research Topics are very popular trademarks of the Frontiers Journals Series they are collections of at least ten articles all centered on a particular subject With their unique mix of varied contributions from Original Research to Review Articles Frontiers Research Topics unify the most influential researchers the latest key findings and historical advances in a hot research area Find out more on how to host your own Frontiers Research Topic or contribute to one as an author by contacting the Frontiers Editorial Office

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Biologics and Biosimilars Xiaodong Feng, Hong-Guang Xie, Ashim Malhotra, Catherine F. Yang, 2022-06-13 Biologics and Biosimilars Drug Discovery and Clinical Applications is a systematic integration and evaluation of all aspects of biologics and biosimilars encompassing research and development clinical use global regulation and more Biosimilars are biological therapeutic agents designed to imitate a reference biologic with high similarities in structure efficacy and safety but also with potential clinical effective and cost efficient options for the manufacturers payers clinicians and patients Most of the top selling prescription drugs in the current market are biologics which have revolutionized the treatment strategies and modalities for life threatening and or rare diseases This book outlines the key processes and challenges in drug development regulations and clinical applications of biologics biosimilars and even interchangeable biosimilars Global experts in the field discuss essential categories and prototype drugs of biologics and biosimilars in clinical practice such as allergenics blood and blood components cell treatment gene therapy recombinant therapeutic proteins or peptides tissues and vaccines Additional features Integrates the latest bench and bedside evidence of drug development and regulations of biologics and biosimilars Contains key study questions for each chapter to guide the readers as well as drug charts for all therapeutic applications of biologics and biosimilars Presents detailed schematic illustrations to explain the drug development clinical trials regulations and clinical applications of biologics and biosimilars This book is an invaluable tool for health care professional students providers and pharmaceutical and health care industries as well as the public providing readers with educational updates about the drug development and clinical affairs of biological medications and their similar drugs

Strategic Marketing For Health Care Organizations Philip Kotler, Robert J. Stevens, Joel I. Shalowitz, 2021-02-17 A thorough update to a best selling text emphasizing how marketing solves a wide range of health care problems There has been an unmet need for a health care marketing text that focuses on solving real world health care problems The all new second edition of Strategic Marketing for Health Care Organizations meets this need by using an innovative approach supported by the authors deep academic health management and medical experience Kotler Stevens and Shalowitz begin by establishing a foundation of marketing management principles A stepwise approach is used to guide readers through the application of these marketing concepts to a physician marketing plan The value of using environmental analysis to detect health care market opportunities and threats then follows Readers are shown how secondary and primary marketing research is used to analyze environmental forces affecting a wide range of health care market participants The heart of the book demonstrates how health management problems are solved using marketing tools and the latest available market data and information Since the health care market is broad heterogenous and interconnected it is important to have a comprehensive perspective Individual chapters cover marketing for consumers physicians hospitals health tech companies biopharma companies and social cause marketing with strategies in this last chapter very relevant to the Covid 19 pandemic Each chapter gives readers the opportunity to improve marketing problem solving skills through

discussion questions case studies and exercises

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